

**REMARKS**

By the present amendment, claim 1 has been amended to recite that the composition is applied so as to substantially cover only the passageway, and to incorporate the subject matter of claim 2.

Support for the added recitation is found in the original application, for example, it is immediately derived at least from the description at page 33, lines 11-15, paragraph 0165, and its illustration in the form of band or plug, as shown in the Figures.

Claim 22 has been amended to replace “orifice” by “passageway” for antecedent basis.

New claim 24 has been added to recite that the composition comprises a water soluble polymer.

Claims 1 and 3-24 are pending in the present application. Claim 1 is the only independent claim.

I. Anticipation rejection

In the Office Action, claims 1, 3-11, 16-19, and 22 are rejected under 35 U.S.C. 102(b) as anticipated by US 5,209,746 to Balaban et al. (“Balaban”).

Claim 1 has been amended to incorporate the subject matter of claim 2, which is not included in this rejection. Further, claims 3-11, 16-19, and 22 depend directly or indirectly on claim 1. Therefore, it is submitted that the rejection is moot.

II. Obviousness rejection

In the Office Action, claims 1-20 and 23 are rejected under 35 U.S.C. 103(a) as obvious over US 6,004,582 to Faour et al. ("Faour") in view of US 5,229,131 to Amidon et al. ("Amidon").

In the Office Action at page 7, line 2, reference is made to the passage of Faour at col. 3, lines 61-64 which states an "inert water soluble polymer coat... partially or substantially completely surrounding the semipermeable membrane and plugging the passageway in the wall" (emphasis added). Further, it is alleged in the Office Action that Amidon suggests pH-dependent or pH-independent embodiments.

Reconsideration and withdrawal of the rejection is respectfully requested. Faour requires that, in addition to the passageway (6), at least a portion of the semipermeable membrane (4) must also be covered by the polymer coat (3). Namely, in Faour, a substantial portion of the semipermeable membrane needs to be covered to ensure that the core will not imbibe quickly after the external coat has dissolved. As a result, Faour fails to teach or suggest a cover composition that **substantially covers only the passageway**, and further, Amidon fails to remedy this deficiency.

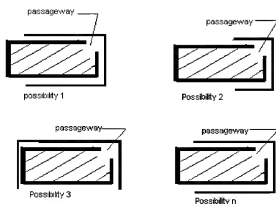
Specifically, Faour states that "[a]t least a portion of the semipermeable membrane (4) is surrounded by a water soluble polymer coat (3) which also forms the plug (7) that completely covers the passageway (6)" (Faour at col. 5, lines 6-9). In its manufacturing instructions, Faour insists on the dual role of the polymeric suspension "which blocks the passageway and forms the polymer coat (3)" (Faour at col. 17, lines 53-54). Thus, the person of ordinary skill in the art

would be taught away from reducing the coverage of coat (3) to substantially only the passageway (6).

Further, all the Examples of Faour use a complete covering of the semipermeable membrane (4) by the coat (3), which also teaches against reducing significantly the coverage of coat (3), let alone substantially eliminating such coverage to the point where the coat (3) would cover substantially only the passageway (6).

In addition, contrary to the assertion on page 7 of the Office Action, Faour does not provide any significant guidance regarding how to reduce a complete coat cover to provide a partial coat cover, except as to a general statement that, not only the passageway (6), but also at least a portion of the semipermeable membrane (4) must be covered by the coat (3), as discussed above (see Faour at col. 5, lines 6-9).

In particular, even if, arguendo, a person of the art had attempted to explore the possibility of reducing significantly the coverage area of the semipermeable membrane (4) (which is denied, as Faour clearly promotes extensive coverage of the semipermeable membrane (4) in order to regulate swelling of its core (5) until the passageway is cleared), it is submitted that a person skilled in the art might think of infinite possibilities for a partial coating according to Faour. For example, a person of the art might imagine exemplary possibility 1, possibility 2, possibility 3 or possibility n as shown below:



However, Faour does not provide any explanation or guidance regarding such variants. Thus, the only relevant guidance found in Faour regarding a partial coating by coat (3) would be a mandate that at least a significant portion of the semipermeable membrane (4), and preferably the whole membrane (4), be covered by the coat (3).

As a result, even if, arguendo, a person of the art had attempted to explore the possibility of reducing the full coverage area of the semipermeable membrane (4) exemplified in Faour (which is denied, as explained above), that person would not find any motivation or incentive in Faour to reduce the coverage area of the semipermeable membrane (4) significantly, and certainly not to an extent such that the coat (3) would cover substantially only the passageway (6). Namely, that person would expect undue difficulties in view of the whole disclosure of Faour. Since Faour insists on the requirement that at least a portion of the semipermeable membrane (4) must be covered, as well as the passageway (6).

In summary, Faour provides no motivation or guidance towards the presently claimed invention, nor any expectation of success. Rather, the disclosure of Faour as a whole, and the actual embodiments in the Examples of Faour, strongly suggest that a substantially complete

cover of the semipermeable membrane (4) by coat (3) is, if not the only workable application, at least the strongly preferred embodiment of Faour.

A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant. See Alza Corp. v. Mylan Labs, Inc., 464 F.3d 1286, 1291 (Fed. Cir. 2006) (legal determinations of obviousness should rely on evidence, not mere speculation or conjecture); see also Innogenetics, N.V. v. Abbott Laboratories, 512 F.3d 1363, 1373-74 n.3 (Fed. Cir. 2008) (even post-KSR, complete absence of proof of motivation to combine will not suffice). Here, there is no evidence of a design need, and no proof of any motivation or incentive to attempt a coated drug delivery system designed as in the presently claimed invention. Rather, Faour would have led the person of the art away from such design, and Amidon fails to modify the teachings of Faour.

In contrast, in the presently claimed invention, the cover composition covering the passageway covers substantially only the passageway, as recited in present claim 1. An advantage of this feature is that it is possible to reduce physical contact or interaction with the polymer that can affect the stability of the active ingredient present in the core, while achieving a same effect of programmed delivery of the active ingredient.

Also, the amount of polymer material, the manufacturing time, and the manufacturing facility requirements can be significantly reduced when substantially only the passageway is to be covered, as opposed to a partially surrounding or full coat as in Faour.

In addition, as explained in the last response, the presently claimed invention makes it possible to obviate drawbacks of a full or partial coating layer as taught by Faour, such as the likelihood that certain beneficial agents will be destabilized by polymers forming the composition because of a chemical interaction in between them. For example, enteric polymers may destabilize beneficial agents such as proton pump inhibitors.

In addition, with respect to the dependent claims, it is submitted that the combined features of each of these respective claims are not taught or suggested by the cited references. In particular, with respect to each of claims 19-22, Faour fails to teach or suggest a cover composition forming at least one of a plug or band blocking the passageway, or a cover composition covering only the passageway, respectively, and Amidon fails to remedy this deficiency. Therefore, each of the dependent claims, and in particular, each of claims 19-22, is not anticipated by Faour, and not obvious over Faour taken alone or in any combination with the other cited references.

In view of the above, it is submitted that the rejections should be withdrawn.

#### Conclusion

In conclusion, the invention as presently claimed is patentable. It is believed that the claims are in allowable condition and a notice to that effect is earnestly requested.

If there is, in the Examiner's opinion, any outstanding issue and such issue may be resolved by means of a telephone interview, the Examiner is respectfully requested to contact the undersigned attorney at the telephone number listed below.

Application No. 10/551,456  
Art Unit: 1615

Amendment under 37 CFR §1.114  
Attorney Docket No.: 053180

If this paper is not considered to be timely filed, the Applicants hereby petition for an appropriate extension of the response period. Please charge the fee for such extension and any other fees which may be required to Deposit Account No. 50-2866.

Respectfully submitted,

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